DEPARTMENT OF HEALTH & HUMAN SERVICES m4890n
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James T. Williams
President
C&C Home Care, Inc.
185 Express Street
Plainview, New York 11803

November 20, 2000

Ref: NYK-2001-22

Dear Mr. Williams:

During an inspection of your drug manufacturing facility located in Plainview, New York, conducted between the dates of October 19 and November 1, 2000, our investigators documented deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). Such deviations cause your drug product, medical oxygen, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act as follows:

1. Failure to test each batch of drug product to determine satisfactory conformance to final specifications [21 CFR 211.165]. Only one cylinder of compressed medical oxygen is tested for strength per day, but more than one manifold group of cylinders (up to 20 cylinders) may be processed in a day, for example: 71 E cylinders and 6 A cylinders were filled on 10/11/00.

2. Production and control records fail to include in-process and laboratory control results [21 CFR 211.188(b)(5)]

   a. Testing records for compressed medical oxygen do not include the assay result.

   b. Testing records do not record all prefill, filling, and post filling test results for D,E, and A size cylinders of compressed medical oxygen.

3. Failure to record a description of the sample received for testing with identification of the location from where the sample was obtained [21 CFR 211.194(a)(1)]. The filling/testing records do not document the specific cylinder of compressed medical oxygen that was tested for strength.

4. Failure to review and approve drug product production and control records prior to release [21 CFR 211.192]. The "reviewed by" portion of filling and testing records for compressed medical oxygen is not signed.

5. Failure to calibrate laboratory instruments in accordance with an established written program [21 CFR 211.160(b)(4)]. There is no established standard operating procedure specifying the frequency of calibration for the oxygen analyzer. The oxygen analyzer is zeroed using room air as opposed to nitrogen.

6. Failure to have a written record of maintenance for the oxygen analyzer [21 CFR 211.182]. There is no record of ever examining or changing the analyzer's filter.

7. Failure to routinely calibrate in accordance with written procedures, vacuum gauges, pressure gauges, and thermometers [21 CFR 211.68(a)].

8. Failure to maintain batch production records for transfilling of liquid medical oxygen from GP-45 vessels to patient cryogenic vessels [21 CFR 211.188].

9. Batch production and control records for compressed medical oxygen do not include accurate information relating to the testing and control of batches [21 CFR 211.188]. Filling records for aluminum E size cylinders report a hammer test is performed on these cylinders.

10. Failure to establish the reliability of the supplier's analysis of liquid medical oxygen through appropriate validation of the supplier's test results at appropriate intervals [21 CFR 211.84(d)(2)].

11. Failure to provide employee training in operations involved in transfilling and testing of compressed and liquid medical oxygen, including training in GMPs [21 CFR 211.25].

12. Failure to establish specifications, sampling plan and a test procedure for the "Heat of Comp." test identified on filling records [21 CFR 211.160].

13. Failure to identify each filling sequence lot of compressed medical oxygen and patient cryogenic vessels with a control number [21 CFR 211.130(c)].

The above identification of violations and the observations on the Form FDA-483 issued at the end of the inspection are not intended to be an all-inclusive list of violations. It is your responsibility to assure adherence with each requirement of the Good

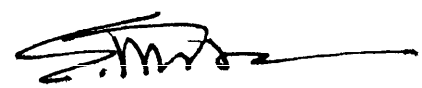
Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to Compliance Branch, Food and Drug Administration, New York District, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Laurence D. Daurio, Compliance Officer. We have enclosed a copy of the Compressed Medical Gases Guideline for your information.

Sincerely,



Edward W. Thomas
Acting District Director

Attached:

Compressed Medical Gases Guideline (Revised) February 1989